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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,103	10/27/2003	James F. Zucherman	KLYC-01077US1	3095

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EXAMINER
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SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/694,103

Applicant(s)

ZUCHERMAN ET AL.

Examiner

James L. Swiger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 68-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/27/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 6-12, 14-20, 23-27, 29-31, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US Patent 6,048,342) in view of Brantigan (US Patent 4,834,757) and in view of Branch et al. (US Publication 2002/0016592). Zucherman et al. disclose an implant capable of being placed between spinous processes having a body (902), a spacer (1016) capable of rotation on a shaft. Note that spokes 1020 do not necessarily *prevent* rotation, but merely help the spacer to fit better (See Col. 23, lines 15-37). Zucherman et al. also disclose a tissue expander (1010) extending from the shaft. Zucherman et al. also disclose a spacer that has a cross-sectional shape that may be considered oval-shaped (see Fig. 93a), has a dimension that could be 8 or 10mm (see table in Column 20), and wherein the tissue expander has a generally increasing cross section as it approaches wing 1032. The spacer is also connected at an attachment (1014) and the attachment includes a device for receiving a wing (1034), and a first wing (1032). The shaft includes an attachment to which the tissue expander is molded (see Fig. 92a). the spacer (1016) is locate between

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a first wing (1032) and a second wing (1004), and see Fig. 92b. Zucherman et al. also disclose an outer spacer (1016) and an inner spacer (1002) capable of being rotatable with one another, as noted above. Also the spacers' structure may be considered have flattened or slightly radiused upper and lower surfaces (see profile in Fig. 93a), and rounded edges.

Zucherman et al. disclose the claimed invention except for a tissue expander being radiolucent. Brantigan '757 teaches the incorporation of radiolucent material for improved X-ray visualization of the device (see col. 1, lines 31-36). The spacer is also capable of being at least partially radiolucent, and would allow a T-shape combined with a radiopaque wing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device the combination of Zucherman et al. '342 and Brantigan '757 having at least a partially radiolucent portion in view of Brantigan '757 to better allow the device to be seen during surgery in the presence of X-ray.

The combination of Zucherman '342 and Brantigan '757 disclose the claimed invention except for a portion that is at least partially radiopaque. Branch et al. '592 disclose a fusion device that is at least partially radiopaque that allows a means for viewing placement of the implant via radiography during surgery. (See par 0009). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. '342 and Brantigan '757 having at least a portion radiopaque in view of Brantigan '342 to allow the device to be better viewed in surgery.

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Claims 2, 13, 21-22, 63, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zucherman '342, Brantigan '757 and Branch et al. '592 as applied to claims 1, 19, and 62 above, and further in view of Brantigan '327.

The combination of Zucherman '342, Brantigan '757 and Branch et al. '592 disclose the invention described *supra* except for wherein the tissue expander and the spacer may be made at least in part of polyetherketone. Brantigan '327 teaches the use of a preferred polyether ketone in implants (see Col. 3, lines 9-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman '342, Brantigan '757 and Branch et al. '592 having at least a tissue expander or spacer made at least partially of polyether ketone in view of Brantigan '327 to better view the device in use.

Claims 5 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zucherman '342, Brantigan '757 and Branch et al. '592 as applied to claims 1 and 19 above, and further in view of Zucherman et al. (US Publication 2001/0012938). The combination of Zucherman '342, Brantigan '757 and Branch et al. '592 the claimed invention except for a spacer having an off-center bore. Zucherman et al. '938 disclose a spacer with an off-center bore so that it may be positioned relative to the central body of the implant (see claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. '342 and Brantigan '757 having at least an off-center bore in view of Zucherman et al. '342 to better orient the spacer in relation to the implant.

Claims 37-41, 43-55, 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. '342 in view of Brantigan '327 and Branch et al. (US Publication 2002/0016592). Zucherman et al. disclose the invention described *supra* except for wherein the tissue expander and the spacer may be made at least in part of polyetherketone. Brantigan '327 teaches the use of a preferred polyether ketone in implants (see Col. 3, lines 9-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zucherman et al. '342 having at least a tissue expander or spacer made at least partially of polyether ketone in view of Brantigan '327 to better view the device in use.

The combination of Zucherman et al. and Brantigan '327 disclose the claimed invention except for a portion that is at least partially radiopaque. Branch et al. '592 disclose a fusion device that is at least partially radiopaque that allows a means for viewing placement of the implant via radiography during surgery. (See par 0009). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of The combination of Zucherman et al. and Brantigan '327 having at least a portion radiopaque in view of Brantigan '342 to allow the device to be better viewed in surgery.

Claims 42 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zucherman et al. '342 and Brantigan '327 and Branch et al. '592 as applied to claims 37 and 47, respectively above, and further in view of Zucherman et al. '938. The combination of Zucherman et al. '342 and Brantigan '327 and Branch et al.

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'592 disclose the claimed invention except for a spacer having an off-center bore.

Zucherman et al. '938 disclose a spacer with an off-center bore so that it may be positioned relative to the central body of the implant (see claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. '342 and Brantigan '327 having an off-center bore in view of Zucherman et al. '938 to better orient the spacer in relation to the implant.

Claims 62, 64-65 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. '342 in view of the combination of Brantigan '757 and Branch et al. '592. Zucherman et al. discloses the claimed invention *supra* except for wherein the body is radiopaque and the tissue expander is radiolucent. Brantigan '757 teaches the use of radiolucent material (Col. 1, lines 30-37) to allow for improved visualization of the implant in use, while Branch et al. '592 teaches the use of radiopaque material for aid in placement of the implant (see par. 0009). These teachings are used together. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zucherman et al. having at least radiopaque and radiolucent material in view of Branch et al. '592 and Brantigan '757 to better view the device while using it in the spinal region.

Claims 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Zucherman et al. '342 and Branch et al. '592 and Brantigan '757 as applied to claims 62 and 64, respectively above, and further in view of Brantigan

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'327. The combination of Zucherman et al. '342 and Branch et al. '592 and Brantigan '757 disclose the claimed invention except for the use of polyetherketone in the spacer and tissue expander. Brantigan '327 teaches the use of a preferred polyether ketone in implants (see Col. 3, lines 9-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Zucherman et al. '342 and Branch et al. '592 and Brantigan '757 having at least materials made of polyether ketone in view of Brantigan '327 to better view the device in use.

### ***Response to Arguments***

Applicant's arguments filed 8/29/2006 have been fully considered but they are not persuasive. With regards to the amendments concerning the addition of a radiopaque shaft, the Branch et al. ('592) reference still teaches the concept using a radiopaque medium and thus the modified rejection above would still overcome the positively recited addition of the shaft in the independent claim.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not



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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



11/13/2006



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